Procedure For Approval of New Drugs

2774. SHRI GOVINDA CHANDRA MUNDA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the procedure/criteria for approval of new drugs in the country;

(b) whether this/procedure is uniformally followed in all systems of medicines; and

(c) if so, the details thereof and if not the reasons therefor?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI. D.K. THARA DEVI SIDDHARTHA): (a) to (c). The procedure/ criteria for approval of 'new' drugs, belonging to modern system of medicine (Allopathic drugs), is given in Part XA of the Drugs and Cosmetics Rules, 1945. this includes examination of pre-clinical and clinical date of safety and efficacy of the 'new' drug generated abroad and within the country.

The preparation of the medicine and the mechanism of action of drugs belonging to other systems of medicine is different and therefore criteria for approval of 'new' medicine belonging to these systems would not be similar. The Drugs Controller (India), who is the approving authority for 'new' drugs, approves such medicines based on examination and recommendation of the experts.

CORRECTION STATEMENT IN RESPECT OF LOK SABHA UNSTARRED QUESTION NO. 825 ANSWERED ON 29TH JULY, 1991

In reply to part (a) of the Lok Sabha Unstarred Question No. 825 answered on the 29th July, 1991, it was inter-alia stated that "salient features of the licence agreements between N.D.M.C. and the above two parties are enclosed". However while sending reply to the above mentioned Question, salient features of the licence agreement between N.D.M.C. and the Holiday Inn was enclosed while the salient features in respect of the other Hotel viz. Hotel Le Meridien was left out inadvertently.

2. The correct reply to part (a) of the Lok Sabha Unstarred Question No. 825 for 29th July, 1991 may, inter-alia, be read as under:

"salient features of the licence agreements between N.D.M.C. and the above two parties are enclosed as ANNEXURE-I AND ANNEXURE-II".

3. Inconvenience caused to the House is regretted.

(M. ARUNACHALAM)

THE MINISTER OF STATE IN THE MINISTRY OF URBAN DEVELOPMENT

New Delhi

Dated the 1st August, 1991

STATEMENT

Annexure - I

Statement referred to in reply to part (a) of Lok Sabha unstarred Question No. 825 for 29.7.91

Salient features of the licence agreements entered into by NDMC with Hotel Holiday Inn.

1. The licence has been granted for a period of 99 years at an annual licence fee of Rs. 1.45 crores.

The licence has been allowed moratorium in the payment on annual licence fees from time to time. The accumulated licence fee is payable in instalments. In the event of default in the payment of licence fee the licensee shall be liable to pay licence fee alongwith interest at 15% per annum.

2. The licensor has absolute discretion to revoke/cancel the licence in the event of licensees failing to make payment of licence fee or any other payment due against them.

3. The land would continue to be on